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DEPARTMENT OF HEALTH SAND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH

THE NEW FDA BIOTERRORISM ACT REGISTRATION AND PRIOR

NOTICE INTERIM FINAL RULES"

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PROCEEDINGS

MS. SETTERBERG: We have a mike here, if you wouldn't mind coming up to the mike so everybody can hear the question?

MR. : You mentioned the transportation terminals, such as truck terminals and express courier terminals are not required to register.

Would that include a marine terminal where it's just held for a day or two before it's loaded on a vessel?

MR. CARSON: Yes, it does cover -- marine terminals are exempt, as well.

MR: : Okay. And--

MR. [PANELIST]: And could I just--excuse me--Lou, does that depend on how long the marine terminal might hold the product in any way?

MR. CARSON: No. We've exempted marine terminals regardless of the time. That's the normal part of their transportation business, and we recognize that things may be held one day, three days, five days--depending on how it's being

shipped in and out.

MR: : The next question is: if we register foreign food facility, and we become a U.S. agent, can we electronically tell you that we no longer want to be a U.S. agent for that firm, without canceling the whole registration?

MR. [PANELIST]: The easiest way to do that would be to call the Help Desk, and tell them that you're no longer that U.S. agent. And then we would end up notifying the facility that that agent their agent anymore, and they'd have to update it within 60 days.

MR: : Okay. Thank you.

[Pause.]

MR: : Hello. I meet the definition as a retailer, however we do have some accounts that distribute product for us. And I do not have to register as per the law here, but can the people that are being distributed to, being that they may be requiring others--the only way that they'll buy their product is if they are, in fact registered.

Can I still register? Am I excluded from registering?

MR. [PANELIST]: You are not excluded from registering. You're not required to register.

MR: : Are there any things that fall on my business, then, that I'm required, that I'd be better off not having that situation?

MR. [PANELIST]: I can't advise you without a contractual agreement--

[Laughter.]

for those people that are covered, and as I mentioned, the primary purpose here is for FDA to know where food is produced worldwide, so that we can notify you if we have information, to reach you. I must say, though, that once we do have information of food facilities, we will use that in our normal course of business to do inspections and other such things that we do on a routine basis.

But there is no other sword of Damocles over your head based on it.

MR: : Very good. Thank you.

MR. : I wonder if you could give an example of situations in which we might actually contact a U.S. agent for foreign food facilities, so we might have a better understanding of the sort of emergency situation that we might be called upon to do something.

MR. CARSON: Okay. All of you should know that the Department of Homeland Security, for example, has a serious of color alert systems, where we go from--we're currently in the yellow alert phase, and we might go up to orange or red.

Oftentimes, when we go from--like last

December, we went from yellow to orange, based upon

December 23. That information alert--and whatever

basis upon which that alert was changed--we in the

Food and Drug Administration notified state and

local health authorities. We also notified our

industry members, based on whatever the substance

of that alert was, and to let them know.

When we do go to a higher state of alert, there may be specific information concerning food, or there may be general information about just the

general infrastructure within the United States.

That kind of information we would notify emergency contacts with, as well.

More notably we, on a routine basis, our Office of Criminal Investigation and other people, work with the FBI and others, and we get all sorts of intelligence information about certain commodities, and certain things that we may want to take closer notice of. And while we're still working this out--we haven't worked up the criteria upon which it would trigger us notifying people through this system, since the system is still being built -- it is likely that we would, in turn, if we got notification that fish coming from Goa--we have credible evidence, or credible information that we are going to start increasing our inspection at the border of those products, we would, in turn, notify U.S. agents from dealing with fish from Goa, as well as other brokers on that very same information.

MR. [PANELIST]: Lou--follow-up. Is it appropriate to have these people understand that we

would also use the U.S. agent in our normal course of business; i.e., they're a representative--they're the designated representative of a foreign firm. We have tested a product and found it to contain a microbial pathogen, and we want to contact that firm. We would immediately know who to go to--someone in the United States that we could communicate with the firm and see wherever the product may have gone to, what possible other countries it may have gone to.

MR. CARSON: Yes, that's a good point that Tom raises. In our normal course of business--I was talking about extraordinary circumstances, perhaps. And Tom is looking at the day-to-day operations that the Food and Drug Administration undertakes. So, in the normal course of business, either in taking samples for analysis, or in other import exams or other means, if we find something out of specs with that product, we would use the U.S. agent as a communication mechanism back to the facility to try and remedy that.

MR: : And how would that differ

from dealing with a customs broker, or an importer--you know, sales agent--handling the product. I mean, isn't that typically the path of communication between FDA food inspections versus bioterrorism inspections?

MR. [PANELIST]: Frequently--sometimes the customs broker is dealing for the U.S. importer; may not know who else is importing the product. The idea of the U.S. agent is they are the overall representative, nationally, of the foreign manufacturer, and would be able to contact the foreign manufacturer and get for us that kind of information.

MR. CARSON: Yes, just to amplify on Tom's point, foreign facilities use multiple marketing and importers, and the U.S. agent would be the single point of contact with the facility, rather than us trying to chase down each and every importer or broker for that particular facility's product. So it does simplify and make us more efficient and effective for us to communicate through the U.S. agent.

That isn't to say that we wouldn't also, in turn, if we also know those other people, let them know. But our primary focus would be with the U.S. agent from an efficiency standpoint.

MR. [PANELIST]: Yes, the whole focus of the U.S. agent is to have one point of contact when you're dealing with a foreign facility. Sometimes it is so difficult, because of language barriers, and having to go through a foreign government, to get rapid information from a foreign firm. The concept of the U.S. agent is that they would be the responsible point of contact to get that for us--one of the concepts behind the responsible U.S. agent.

MS. SETTERBERG: I think--Mike, did you have a comment? Maybe you can come up to the mike.

Mike Marley is one of our technical folks in the import arena.

MR. MARLEY: We're also starting to get communications now with the EU, from their rapid alert system. And so we might also find--that's another source of information, where the Europeans

are telling us there is a problem with a certain product, or company, and that we may be concerned over whether or not some of that product may have ended up in this country.

So we're getting information--yes--through governmental sources, as well.

MS. SETTERBERG: I think this gentleman in the beige coat has been waiting patiently.

MR: : It was mentioned that you're going to reopen the comment period, maybe next week? For how long? Is that decided?

MR. CARSON: Minimum 30 days, and maybe 60 days--I'm not clear. But it's certainly 30 days comment period.

MR: : And one other question: could you state FDA's position on confidentiality of the registration numbers?

MR. CARSON: The statute requires FDA to not disclose the registration number for any facility, and part of the reason for the passwords and the PIN numbers and all of that is to have the integrity of the system so it can't be hacked into

and inadvertently shared--that information--with other people who do not have that password information.

So, the question that has usually come up is: can I share my registration number with a supplier who's asked me for it? And the answer is: yes, you own it. It is your property. you may use it in any way you do other business information that you share with your suppliers or other people that you have contracts with.

FDA is obliged not to share it with the public. We may share it only with other Federal or government officials, based on an agreement with them that they would not, in turn, disclose it in a public forum.

So, again, this information is to be used for us to best respond to emergency and other kinds of information, and oftentimes we do need to share that with state and local, or other country officials. And that's the only time we can share it.

MR: : Would you say it's within

your, say, guidelines to put the number on a commercial invoice, just to facilitate the passing on of the information to customs brokers.

MR. CARSON: Well, we will be talking next about prior notice. And, within prior notice, the registration of the food facility, as well as the shipper, is going to be required information through the ABI/ACS system, or the FDA PNSI system. So there is a way where that information does need to be conveyed back to FDA on the shipment of those foods from abroad.

MR:

MR:

Thank you.

Can you provide the

[Pause.]

perspective of the situation where a U.S.

manufacturer exports a product to a foreign country that's rejected, and that the need for a registration number from the customer for that product to come back into the U.S.?

MR. CARSON: We haven't quite had it expressed that way, but we certainly have met with a number of businesses that are in the--shall we

call--the gray market arena, in which U.S. goods have been sold abroad; some goods are not completely sold out and they're U.S. return goods for resale here in the U.S. And those either consolidators, or salvagers, or whatever term is appropriate, are trying to comply with the prior notice rules--which we will be discussing next--and one of the requirements, just as I responded to the previous gentleman--you would be required to have the registration information of that facility that produced that product.

So, if you're producing the product here in the United States, domestic facility, you would need to have a registration number. It would seem to me that since it's a one-to-one correspondence with the person who is rejecting it, you could easily satisfy the prior notice, because you would know your registration number for your facility.

But in the case of the gray market people, they did not own the facility; they did not necessarily know what the facility is, other than one might in the labeling or packaging, produced in

Bryn Mawr, Pennsylvania, by the Hershey Cupcake
Company, and they don't have a registration number.
So they're trying to figure out how to respond to
that. We're still working with them on how that
might work out.

[Pause.]

MR: : I have a question about [inaudible] registration's, and more specifically about the emergency contact phone number. And my question is: are there any special requirements for that phone number? Like it should be answered by a human being, 24 hours a day, seven days a week?

MR. CARSON: We've had many questions on that. Obviously, that's the ideal. We recognize that no one is at their phone 24 hours a day, seven days a week.

The requirement is that that phone be regularly monitored so that that that information can be got at in a reasonably short period of time; especially, the question has come up with small business that cannot afford to have an answering service while they're off hours, even if it's

normal business hours. We don't expect someone to be always at that phone each and every time, so there may be voice mail.

But, suffice it to say, if we do leave a message, we would expect a prompt response; so, some reasonable time for someone to monitor that number and to respond to FDA is what's expected.

MR: : Okay.

My second question is about Section 11, where you list the type of food is made. You obviously purchase other ingredients to make that food. Do you also have to register those ingredients that you store in your facility?

MR. CARSON: No, the focus here is what your facility produces. If you produce ice cream, that's dairy products. You don't have to include the nuts and the chocolate that you might put into that, because that's what you're producing.

MR: : Thank you.

MR. [PANELIST]: Lou?

MR. CARSON: Yes.

MR. [PANELIST]: Just to amplify that: I

think the purpose is if your a commercial business is as a warehouse, you would have to list that.

But if you are simply warehousing the raw materials that you use in your manufacturing facility, you do not have to list yourself as a warehouse and list those types of food.

[Pause.]

MS. : My question has to do with quality-control samples. We manufacture dairy cultures here in the United States, and export them to Canada, to various dairy-producing companies in Canada. They do not produce product that is, in turn, re-imported into the United States. But they do occasionally have quality-control issues that they want to return a sample; the cheese or yoghurt that they've manufactured, to our research facilities in the United States.

And at this point in time, the way the law reads, it looks like that each and every one of those facilities would have to register? They're producing the cheese. It is not our culture that's returning, it's the cheese or the yoghurt that's

returning. It will not get in the food chain. It's basically coming back for R&D.

MR. CARSON: I think, if you're reading the rules, this actually applies to prior notice. It does not apply to registration.

 $$\operatorname{MS}$$: Oh. Well, in order to do the prior notice--

MR. CARSON: Well--

 $\text{MS.} \hspace{1cm} : \hspace{1cm} \text{--they need to}$ register--the way I read the rules.

MR. CARSON: Well, we are trying to work through that system so that trade samples that are shipped here, or quality-control samples that are shipped to the United States, where that food facility does not produce products for consumption in the U.S. would not be required.

So, as you'll--we're sort of jumping ahead, but there is both an electronic review of data that comes in--so you're right: initially the system would flag that, but perhaps then the human review of that information would note that this product is not for U.S. consumption, it's simply

for a trade purpose or for a testing purpose.

But, there is a little bit of a glitch there. You're right. The two rules do have that difference. Prior notice is for all foods, regardless of what purpose; even if it's for import for export. Whereas registration is only for U.S. consumption.

So we need to work out some way so that prior notice can be satisfied, but you don't--we don't need to require that facility that doesn't sell foods for U.S. consumption to register.

MS. : Thanks a lot. We've been labeling thing as "not for human consumption," but I'm glad that you're looking into that. Thank you.

MR. CARSON: I haven't said we've solved it. I said we're looking into it. Yeah.

[Laughter.]

[Pause.]

MS. : Hi. I want to get some clarity on agricultural producers that do processing on their farms.

Cider manufacturers who wholesale; but

it's at their place of residence. Are they exempt?

MR. CARSON: [Laughs.] Well, again, you have to start off by first looking at the function that they serve. If they are a processor, then they're covered. There is an exemption, however, if that processing is done at their primary place of residence.

So, yes, if it is their residence, they're actually performing the cider process at the residence, they are exempt.

MR. [PANELIST]: Ah, could I--

VOICE: [inaudible]

MR. [PANELIST]: --yes--that's my point.

I doubt if they're pressing cider in their living room.

MS. : Well, it's an attached room to their house.

MR. CARSON: Well, then that would qualify.

MS. : It's not a barn.

MR. CARSON: I mean, obviously we'd need an interpretation, but--and we have had these--the

garage is where they're doing it; that has actually been interpreted as their residence.

Okay. So, for right now, we'll give you a dispensation and say, yes, it's--

MS. : [Laughs.]

[Laughter.]

MS. : Okay. What about a potato grower who washes, sorts and bags product for consumer use? But it's at their--you know, they live on their farm. I mean, it's not in their home, but it's basically going to go next to consumers.

MR. CARSON: Again, I think we had some slides that showed you that. If they are actually washing and sorting and then bagging, that would probably fall into the processing part, and that facility where they do that would need to register. But the growing of the potatoes—they were just harvesting and putting them into trucks or into bins to ship off, and for that to be done, that would be under the exemption. But it sounds like they're actually in the sort of the peeling,

washing, trimming kind of arena, which we would classically put under processing. And especially if they're bagging it for consumers, then that would seem to fall under the processing, and they would be required to register.

MS. : Okay. And my last question: people who use contract manufacturing sites, and are the business of record, they don't have to register, but the locations they use should be registered.

MR. CARSON: Correct. The owner, operator or agent in charge of that facility is required to register. Someone on their behalf may be authorized to register.

So, you have a business interest with that facility. It's--we would appreciate if you notify them that they need to register. In some cases, some businesses that have their products in warehouses have chosen to register that warehouse on that warehouse's behalf. But, nonetheless, we would ask you to have them register. It is their responsibility and not yours.

MS.

: Okay. Thank you.

[Pause.]

MS. : Our agency had registered about 40 facilities, and for each of the registrations, I've put in a preferred mailing address. And, apparently, a confirmation for the registration was sent, but not to the preferred mailing address. It was sent to the facility. I did get an e-mail--like a mass e-mail--that, you know, said there was a mix-up.

Some of those made their way to the central office, and I checked them off that they were supposed to be registered, and sent them back. But some of them didn't. And my question was: will their registration be cancelled if the confirmation wasn't sent?

MR. CARSON: The answer is no. We have run into a problem. The way we had programmed the system was that--again, this whole thing was done in a very accelerated time scale. And so we had to get an IT system up and running as soon as possible.

What we did was program into that system, inadvertently, that as we were trying to register each facility, we wanted to notify that facility of the data we had in the data base for them to verify.

We failed to catch if there was a preferred mailing address for this communication to go there. So we have sent out a mass note. We put it up on our web site. We did tell people they need not respond to that initial verification notification. There will be a subsequent going to those who have a preferred mailing address.

So, hold off. Nothing will happen until we send you something to your central location so that you can verify that.

MS. : Okay. Thank you.

[Pause.]

MR. : I'm an animal food maker, and I just want to make sure everything's clarified in my area.

If it's on a residence, a farm, if I render, slaughter, or sell my product over 51

percent direct to non-profit organizations, I don't have to register?

MR. [PANELIST]: No--okay, I need some more background on this. You are--

MR: : Ribopack--I manufacturer animal consumptions, but we also farm. The business is on a residence. We also process a complete package for frozen foods for zoology industry, which is 80 percent of my business. And you're saying that I don't have to register.

MR. CARSON: I'm not saying that yet.

MR. : Because it's a farm. I'm on a farm.

MR. CARSON: Okay. Well, it's--

MR. : And it's a part of the residence. I slaughter and render.

MR. CARSON: Okay. But now slaughtering and rendering is not a normal procedure of a farm. So you're going beyond the normal procedure for a farm.

MR. : Right. But it's still on a residence.

MR. CARSON: Well, all farms are residences. But it's for a commercial--

MR. : Right.

MR. CARSON: --that you're doing this.

MR. : Right. Right.

MR. CARSON: And from what I understand, I would say, yes, you have to register.

MR. : Okay. I wasn't sure.

Because you say if 51 percent of your business is

direct to non-profit organizations, which--zoos are
non-profit organizations, then I'm exempt.

MR. CARSON: Okay.

MR. : If I'm on a farm doing it, then I'm exempt. If I'm on a residential area--which the business, the house is right there in front of the business, then I'm exempt.

So I just want to be sure I'm clarified on all this.

MR. CARSON: Yes.

VOICE: [Off mike.] The words you said--"the house is in front of the business." They're two separate entities.

MR. : Well, it's part of the residence. It's--

VOICE: You're rending in your house?

MR. : No, but I'm rendering right there on the property.

MR. CARSON: Yes, but that not your residence. I mean--

MR. : Well, if I go in there and live in it, it's a residence, am I right?

[Laughter.]

If the house is here, and the business is in front of the house, not even a hundred yards away--but I'm just making sure.

MR. CARSON: Right. Now, I'd say register. When in doubt, register. There's nothing that's--you know, there's no charge for it--

MR: : All right.

MR. CARSON: -- and this way if something were to occur--

MR: : Because when the FDA shows up at my place and starts [inaudible] bags and

going, "What the hell's going on here?"

And--was it you? Or one of your co-workers had come up, and after this was a retirement, with Dr. Zirkle had informed us that we had to put stuff on our boxes "do not feed to cattle or other ruminating animals" because of the BSE issue--

MR. CARSON: Correct.

MR: : --and then I get a thing, well we're supposed to register. I'm going "Wait a minute, now." You're giving me criteria that say I don't have to register, but as a common courtesy you want me to register because I'm a commercial business, you want me to do so.

MR. CARSON: What you need to do is outline--if you're figuring that you do not need to register--

MR: : No, I'm just curious.

Because the people that I do business with are going to say, "Well, do we register or not?"

MR. CARSON: Okay. From the information I have, I would say, yes, you need to register--

MR: : Okay.

MR. CARSON: --unless you show me, you know, reasons why not. But the way I'm reading it right now, yes, you need to register.

Now, you're saying "people that you do business with?"

MR: : Well, I have--out of one business we have four corporations that run out of one plant. We have the rendering part, we have the slaughter part, we have the packaging part--and then we have the farm.

MR. CARSON: Mm-hmm.

MR: : But then I send products out to like, Omar's Pride. Do they have to register, or can they fall under mine?

MR. CARSON: No, they would have to register--

MR: : On their own.

MR. CARSON: --on their own. Yes.

MR: : Okay. But I have to

register--where I manufacture a finished product for the two businesses--

MR. CARSON: Correct. That facility.

MR: : Those two names have to be on there--on my register for you people.

MR. CARSON: Correct, if I'm reading your question. Yes.

MR: : Okay. Thank you.

MS. SETTERBERG: It sounds like, sir, that one of the things that might be helpful is this afternoon, after we're done, there's a period of time where you can sit down with some of these folks and go through the registration process, then we can kind of sort through that with you.

So if you want to stay to do that with us, that might be helpful.

MR: : Well, it's not really hard to figure out, because he put it there as in--if you have one business, and you go under a separate name with the other business, but you're still supplying--that corporation's still supplying the same product, then both [inaudible]--

MR. CARSON: Correct.

MR: : I mean, that's not hard to

figure out. I was just confused about the farm, the rending, the slaughter and all that, when FSIS comes and sees me, and APHIS comes and sees me on a regular basis.

MR. CARSON: But your rendering facility comes under the FDA aspects, and then also--

MR. CARSON: Okay. In regards to the passing of diseases to other animals--that type of thing.

 $$\operatorname{MR}:$$: Yeah. Because they're looking for the BSE.

 $$\operatorname{MR}$.$ CARSON: For the BSE, it would be--right, the FDA aspect.

MR. : Because APHIS, actually--APHIS is in charge of that. They're the ones who come and say, "We want samples," and this that and the other thing. Compliance just comes in--

MR. CARSON: Well, okay--for--

MR: : --compliance comes in and

says, "You have 'animal consumption' on your packages," this, that and the other thing--you know. But I get to see them all the time.

MR. [PANELIST]: Right. Yes, you have different businesses there. you have the slaughter aspects of it, and then you have the rendering aspects of it.

MR: : Right. And then the processing aspects.

MR. CARSON: Correct. Correct.

MR: : And you people

occasionally.

MR. CARSON: Correct.

MR: : Okay. Thank you.

MS. SETTERBERG: You get us all. Thank you. [Laughs.]

[Laughter.]

[Pause.]

MS. : [Off mike.] I work for a bottle water manufacturer, and my question's on "facility?" Do our spring sources need to be registered?

MR. [PANELIST]: No.

MS. : Definitely no.

MR. [PANELIST]: Correct. No.

[Pause.]

MR. : Hi. I represent a

retailer. I have two quick questions.

We certify a lot of our vendors and go visit different places. Does a warehouse and a distribution center need to be registered--for food?

MR. [PANELIST]: Yes.

MR. : Okay. And the second question: is there a place on the website to change your password or PIN number, if you--

MR. [PANELIST]: Yes, you can change your password.

MR: : Okay. Thank you.

[Pause.]

MR: : This might be more under the prior notification section, but we're an international mail order company for food supplements. How will you be handling returns?

Will you be addressing that?

MR. CARSON: That will be addressed in the prior notice section--coming up shortly.

MR: : Okay.

MS. SETTERBERG: I know we're going a little bit over, but I think it's important to have other questions. We will have another Q&A at the end, with prior notice. And Lou will be around, too, for anything that goes under registration.

Yes, sir?

MR. : you had said the marine terminals are exempt?

MR. CARSON: Correct.

MR: : At what point--what's the storage criteria, where they become a warehouse?

Is there a length of time?

MR. CARSON: Don't go there.

[Laughter.]

MR: : Well, I mean something that we need to consider--correct?

MR. CARSON: Well, the--if you're going to--one answer to that question is that it comes

down to a bonded warehouse. And if you were going to be at the marine terminal, there are some either bonded or secure locations that we would store materials, those would have to be registered.

But, as a marine terminal in the normal course of business of its transportation function, you need not register.

MR: : And if you're registered, should you cancel the registration?

MR. CARSON: That would be ideal--yes.

MR: : Okay. Thank you.

[Pause.]

MS. : [Off mike.] I have a corporate question. The lady just--she mentioned your exemption for the foods or products within your home, but you did not specify that was valid for international foods that are imported but are, you know, basically processed in the home.

MR. [PANELIST]: I do believe that will be talked about during the prior notice, but I--it is my understanding, Joe, that if you are sent food from overseas from your mom, or your aunt, and it

comes to you -- or --

MR. CARSON: No, you're saying this is a business, right?

MS. : Yes, but--you know, wines--most of them are businesses, but some of them you can bottle wine from your home. Would that fall into an exemption, or would they have to register their home address?

MR. CARSON: In the case of wine, you're going to have to register. Because that processing, even though you might have the press in your basement and all that--

MS. : Yes.

MR. CARSON: --you're processing a thing, and we're going to require you to register.

MS. : All right.

[Pause.]

MS. SETTERBERG: Okay.

Next we're going to take a 15-minute break while we change around up here. So please feel free to have coffee. The restrooms are straight down that incoming hall and to the left.

And we'll be back in a few minutes.

[Taping stopped; taping resumed.]

MS. SETTERBERG: We have a few folks coming up here to join our panel for questions.

So, if any questions--would you like to come up to the mike?

MR: : Hello. It says here "Food that is imported and exported without leaving the port of arrival until export is exempt from prior notice."

My question is a technical one. If you import on one side of the river in a different port code than the one you're exporting from--you're crossing--

MR. [PANELIST]: That's a T&E.

MR. : It's a T&E?

MR. [PANELIST]: IE--it's exempt.

MR: : Okay.

MR. [PANELIST]: But, yeah, the T&E, whether it's across the river or across the country, it's the same.

MR: : From one port code to

cac

another, it's --

MR. [PANELIST]: Yes.

MR: : Technically, it's not

exempt, then.

MR. [PANELIST]: Correct.

MR. CARSON: Now, if you're considering Philadelphia and Camden, we don't use 1107.

MR: : Oh, I'm actually talking,

specifically, about Chester and Salem.

MR. CARSON: Okay.

MR. : So it's not exempt.

MR. CARSON: No.

MR: : Okay. Thanks.

[Pause.]

MS. : I represent Canadian

shippers using express carriers.

In a scenario where a shipper files using the website, and then the broker files the entry via ABI--

MR. [PANELIST]: Mm-hmm.

MS. : Who is subject to any

fines or penalties assessed, based on providing

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inaccurate information?

MR. [PANELIST]: The--I believe that would be the submitter of the information, and that would be--to my definition, I believe the person who put in the data on the website.

The only thing the broker is going to be doing--about the worst they can do is transpose two numbers on the confirmation number. So the liability would be whoever provided the prior notice.

The whole thing with the submitter versus transmitter was to cover the liability issue. The transmitter is somebody who is essentially keying in data--which is largely what the brokers will be doing in this. The submitter is the person who has knowledge, whether it's the importer or the foreign source.

MS. : Okay.

Umm--throughout this whole process there's been a lot of conflicting information with regard to, you know, a broker may give a shipper information as to what's required; shipper would

called FDA to get clarification on what's required; and then everybody has their own interpretation from reading the regulations, as well.

Would there ever be any plan to--and, for example, if I'm asking you a question, a lot of it is verbal. Is there any plans to have anything binding, in terms of--unfortunately, I can't think of a specific example--

MR. [PANELIST]: If Lou--Lou, do you have--you know, how we're going to get additional guidance and to clarify--

MR. CARSON: The Q&As.

MR. [PANELIST]: Yes, but Q&A is on the website.

MR. CARSON: In fact, that's what some of the--the gentleman over there was doing: capturing a lot of the questions that are being asked at these outreach meetings, because in addition to written comments, some of these things will end up as Q&As on the website.

MS. : Okay.

MR. CARSON: One issue--largely, the

Canada, is one of the problems we're having, not so much in the Philadelphia area, but on the northern border particularly, is there are some filers who still continue to send foreign-based consignees.

And they have been sending--Customs has been sending out admins since, I think, '94. This causes rejects. It is getting increasingly more difficult.

Customs allows it at time of initial entry, as long as you correct it by summary. It doesn't work with FDA entries. So, that's a big area of concern, is making sure that when you're doing your entry data--your ABI entry data--you are using a U.S.-based--the importer of record still can be foreign.

MS. : Mm-hmm. we have quite a few shippers who ship goods from their home--personal business. So they themselves would be exempt. However, the products that they ship would require prior notice because it's food.

MR. [PANELIST]: Mm-hmm.

MS. : There is a bit of a

paranoia in a log of registered food facilities for them to give out their registration numbers.

MR. [PANELIST]: Right.

MS. : You know--gift baskets or what have you--that are being shipped. So shippers are in Canada are concerned about not being able to get the number from all these different facilities.

MR. [PANELIST]: The--in that scenario, and if a manufacturer is really concerned, the manufacturer could actually submit the prior notice data. So if I'm the manufacturer, and you're shipping, and you tell me "I'm shipping 50 cases of your stuff," I could submit the prior notice data if I have it, and then give you a confirmation number, which is good for that one shipment. And I'm not compromising my registration number.

As a manufacturer, of course, I'm taking on a lot of extra work. That's about the only way I know that you can--you know, if you truly want to keep your registration number secret, you have to essentially assume the duty. Because the moment you hand it to a third party--be it a shipper or a

customs broker--you've truly--whatever--you know, you should have confidentiality agreements, but, you know, you're potentially losing control.

MS. : So that number can't be abused, if it were to be given out to anybody--

MR. [PANELIST]: The prior notice?

 ${\tt MS.}$: The registration number itself.

MR. [PANELIST]: Yes, it can be abused.

MR. CARSON: Any number can be abused.

MR. [PANELIST]: The shipment number is only--you know, a shipment number is valid for a couple hours--

MS. : Mm-hmm.

MR. [PANELIST]: --or a couple of days if it's a sea entry. So, you know--

MS. : So, come August, you know, people sending gift baskets, etcetera, into the U.S.--

MR. [PANELIST]: [inaudible] having--there is policy discussions going on currently on how to handle gift baskets. Because i know that's an area

that has come up.

MS. : Okay.

MR. [PANELIST]: And I don't know what the final--you know, the outcome of that discussion is going to be.

MS. : Sorry--I've just got one more question, because I've got a flight to catch.

So will there be any change in terms of samples that are shipped, or gifts shipped, come August? Will there be any change in the way it's handled? Or just regular enforcement.

MR. [PANELIST]: Well, that's why this is an interim final rule. when the final rule comes out, that's when, you know, hopefully, most of these questions have been addressed.

MS. : Right.

MR. [PANELIST]: I'd just like to--two things. I believe--you know, we are aware of many of these things. I believe Lou, earlier today, mentioned that--you said "samples being shipped." We realize in the course of business this happens, and we have to find a way to deal with them.

But to get to your--and so when the final rule comes out we will address these issues as best we can.

But I do want to stress to

everyone--something that was mentioned here--the

questions we're getting at this session are

questions we're getting at other sessions. And

people in towns where we're not having sessions

want to hear the answer to these questions.

There is a list of Q&As--questions and answers--on our website, and that is our considered opinion of the interpretation of the interim rule.

And I would urge all of you to go through these to see if there is anything that particular affects your business.

I'm sorry.

MS. : I'm done. Thank you.

MS. SETTERBERG: I'm thinking it would be very important, too, during the open comment period, if you have an appropriate comment--even though you've talked at these sessions--to make sure that you make comment. Because sometimes the

volume of the comment that comes to us may have a way of affecting our action on it. You know, if we hear it from one place, that's one thing. But if we hear it from multiple places, that helps.

So, I would encourage you not to just rely on commenting here.

[Pause.]

MS. : My question has to do with some complaints that we've had from our foreign locations about--they're trying to do prior notice entries through the PNSI system from the website, and what they're trying to send is food additives. And they've complained that the tariff codes for the particular items that they're trying to send are not--they're not able to put them in; or, you know, the codes are not there.

For example, we had a situation with the hydroxypropymetholcylose, and they said they don't know how to enter it, because there's not enough choices for them.

MR. [PANELIST]: Okay. A couple of issues there.

One, if--these things are young. We have the flags that were referred to before, as to whether or not PN is required, or may be required. These things are constantly being changed. One letter came for me the other day that I passed on, you know, for classification was gaseous hydrogen. Okay? You know--hydrogenated vegetable oils, okay? It requires it. So that one's getting flagged.

So if you have flags--things that, you know, think need to be flagged, you can e-mail--I can give you my e-mail and I'll pass it on to the people that have to do that.

Also, we're running into some problems where there were things in the FD-3 tariff flag, which may require FDA and PN. And we're finding a few products which really require a fee, but don't require PN.

And right now you can't--you either disclaim the whole thing or you have to report the whole thing.

There are changes being worked on between ACS and FDA; one to allow reporting of unflagged

tariff codes, because right now they will reject.

If you come up with some tariff code that is not flagged and try to send it, ACS will currently reject it. That we are working on, trying to get a mechanism with them to accept just--they won't edit it, they'll just pass it on to us.

And then the issue of the FD-3s that are reportable to FDA, but are not really subject to prior notice. That one is--that's going to take a little bit of engineering, but it's being worked on.

MS. : Okay. So if we discover these, we should, you know, e-mail the agency and let them--

MR. [PANELIST]: Yes.

MS. : --you know, aware of the situation. Okay.

My other question, or comment, was about what you were discussing just with the prior person about the confidentiality of the registration numbers, and about if you were concerned about that you should do the notice yourself.

And we use Federal Express and UPS and DHL a lot. And, you know, it's really--we're unable to do it because we don't know what airplane they're going to put the box on, you know. So, I mean, is there--has there been any issues, or are people concerned about the fact that we have to give FedEx the registration numbers, or--

MR. [PANELIST]: Well, I mean--

MS. : --has there been--you know, I haven't heard any discussion about that, other than that--one mentioned that.

MR. [PANELIST]: This goes on now with LACF--you know, filing and SID numbers. All these numbers get given out. And there is a--you know, you have to have a certain assumption of confidentiality with the broker. And as far as what plane--you know--

[Pause.]

--prior notice?

MR. [PANELIST]: They have to know when it's shipped.

MR. [PANELIST]: Yeah. I think you

can--again, it would be a complex business arrangement, but you would have to be able to do a split where you provide part of the information and they provide part of the information.

MS. : Well, I think right now what we're doing is just telling them, you know, what we know about the shipment--

MR. [PANELIST]: Mm-hmm.

 ${\tt MS.}$: --and then they do the notification--

MR. [PANELIST]: Right.

MS. : --because they know how it's actually arriving, when it's arriving--all that. We just hand them the box and say, "Here's the information."

But, you know, we have had some concerns that we're kind of just giving out all the--you know, the registration numbers, you know, to FedEx, and we don't know if there's any--you know, there's no arrangement of confidentiality there with them.

So it's just something, I guess, that I just wanted to bring up that we're concerned about.

MR. [PANELIST]: Joe, you might talk to this. I mean, isn't there a general, under their Customs license, a confidentiality of--

MR. [PANELIST]: Trade Secrets Act prohibits--

MR. [PANELIST]: Yeah--thank you.

MS. : Okay.

MR. [PANELIST]: --willy-nilly giving that stuff out. You don't see it written on the mens room wall or anywhere.

[Laughter.]

MR. [PANELIST]: You haven't been in our building.

[Laughter.]

MR. [PANELIST]: Well, most people at Customs can't write, so it's--

[Laughter.]

of a shipment that arrived on the west coast and moved inland to Oakland on an IT entry. And the prior notice confirmation had to be accomplished prior to it discharging on the West Coast.

If you have a T&E entry for discharging, say, on the East Coast, going up to Canada, the prior notice is done prior to arrival on the East Coast.

If that entry is then change to "consumption," can that same prior notice confirmation number be used for the consumption entry?

MR. [PANELIST]: Yes.

MR. [PANELIST]: I believe it can.

MR. [PANELIST]: Yes, the confirmation number is for the shipment.

MR. : Okay.

MR. [PANELIST]: Yes, the product has not changed.

MR. : If the--

MR. [PANELIST]: Because on a T&E we don't even know who the ultimate consignee. You're just telling us it's going out of the country. We don't know who, in Canada, or who, in Mexico, is going to get that product.

MR. : When the consumption entry

is done, if they split the bill of lading--say it's four containers; two do continue to Canada and two are entered for consumption. Is that confirmation number still going to be good?

MR. [PANELIST]: Yes, because under--

MR. : You can amend the quantities, correct?

MR. [PANELIST]: Yes, I know. But under a single--right now, a single IT can end up in 10 consumption entries under the current environment, because it's totally outside of prior notice considerations.

So, yeah, that is not an airtight accountability. We're not trying to count, saying that there were 347 cases here, the consumption entries better add up to 347. They better not add up to 947.

MR. : You're more interested, then, in the--

[End Tape Side A]

MR. : --manufacturer product code.

MR. [PANELIST]: Pretty much. If you're looking from the BT point of view, you're looking at it before it enters the country is where you're really trying to get at it. The problem is--one of the reasons they went to the ITs is for just the reason you're saying. Sometimes they get converted to consumption, and sometimes they disappear.

MR. : Thank you very much.

MR. [PANELIST]: Things get lost on the way to Canada.

MR. [PANELIST]: Yes.

[Pause.]

MR. : Hi. I just wanted some clarification on my earlier question. We're a vitamin mail-order company, and we ship to some customers internationally--and when they wish to return our goods.

I noted on one of the slides it said to basically go onto the FDA website and obtain a prior notice number and attach that to the package so it can go through the international mail system.

The only reason I'm questioning it is that

sometimes the bottles are sealed. I mean, if the manufacturer's seal is still on there, obviously there's no processing taking place; there's no manipulation of the product overseas. They're being return as U.S. goods, untouched.

Now, does--I have to put standard procedures in place now that my customer service people will have to follow. Is this something our international customers are going to have to do under these circumstances now?

MR. CARSON: Yes, but you have to provide the prior notice. And I can just tell you that we've gotten product--we've gotten products back--it happened to be not a food product--but it was such a darn good counterfeit it fooled the manufacturer. And they ended up redistributing it.

MR. : Mmmpphh.

MR. CARSON: That's how good the counterfeit was.

MR. : Okay.

MR. CARSON: Except for the fact that the product wasn't right. But the package was perfect.

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MR. : Thanks. Okay. So it's fair to say, then, we can put the onus on our international customers to log onto the website and obtain their own prior notification number.

MR. CARSON: Right. And, again, the only catch there is giving out your registration number, which you may or may not want to do.

 ${\tt MR:}$: What registration number would we have to give out?

 $$\operatorname{MR}.$$ [PANELIST]: He's not the manufacturer.

MR. CARSON: You're not the manufacturer of the product originally?

MR. : Originally, yes.

MR. CARSON: Then it's your registration number.

MR. : Our U.S. registration number?

MR. CARSON: Yes, because you're the manufacturer.

 $$\operatorname{MR}.$$: Okay, that will have to be attached to the prior notification number on the

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return of the goods.

MR. CARSON: Well, it has to be in the prior notice submission.

MR. : Okay.

MR. [PANELIST]: As the manufacturer, so you would give your registration number as the manufacturer of the goods. The shipper, who would be the guy returning the package overseas--

MR: : Yes.

MR. [PANELIST]: --they wouldn't have to have a registration number per se--

MR. : Right.

MR. [PANELIST]: --because they're not the manufacturer, and they're just a shipper returning--

MR. : A consumer. It's just a consumer.

MR. [PANELIST]: Right.

MR. : Okay. And if someone doesn't have web access to do this? If it's some--

MR. [PANELIST]: Well--

MR. : --place out there in the

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world? What's the alternative to going onto the website and getting this.

MR. CARSON: There is a paper--there is the paper form, right?

MR. [PANELIST]: Umm--it has to be submitted electronically, prior notice.

MR. CARSON: Right now--yeah.

MR. [PANELIST]: If they're on the top of Mt. Everest, they're screwed.

[Laughter.]

It's as simple as that, I think.

[Laughter.]

MR. [PANELIST]: If they're up there they're not going to be able to get a post office to send it to you.

MR. [PANELIST]: They probably could e-mail the prior notice center; or call the number.

 MR . : No, they don't have e-mail.

MR. [PANELIST]: If they have e-mail they could do the--

MR. [PANELIST]: That's true, too.

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MR. : Okay. thank you very much.

[Pause.]

MS. : I just had some questions related to registration, so I hope you don't mind if I go back.

One of the questions--when you had the screen up to register, I saw that you had a button for "search registrations." What does that allow that person to do? Can somebody go back and find out information about my firm?

MR. CARSON: Good question.

MS. SETTERBERG: Larry's going to answer your question.

MS. : Okay.

MR. DUSOLD: Whenever you do a search, you're allowed to search by zip code and a lot of other things. So, for example, a large company like Kraft, or General Foods, or something like that, with international operations, could go and search all 500 of their facilities by manufacturer name. If they had, say, three facilities in one

state, they could search by zip code in the state, or by state name. So it allows you to search different options for those companies that have lots of registrations.

MR. [PANELIST]: But only your own.

MR. DUSOLD: Only your own. you can't search anybody else's.

MS. : All right. That was my concern. If I was a potential terrorist, that would be an easy--

MR. DUSOLD: Yes, that was a question.

No, you're only allowed to search your own
registrations and no others.

MS. : Okay. That's [inaudible]. Thank you.

The other question I had was if we're a manufacturer and we store raw materials off site, but it's in a leased building that is subdivided into three sections, which--some of the sections are unrelated to manufacturing of food materials, and there's only one address.

Would we be required to register our

section, that doesn't even have a separate address, of that building?

MR. CARSON: I think yes.

MR. [PANELIST]: Yes.

MR. CARSON: I mean, you're storing food off-site from your manufacturing site. It's a separate facility. It's as if your company had two different facilities. The second one would have to register. You'd use the central address for the warehouse that you are using.

MS. : So, if we have--the bill of ladings actually have our manufacturing address on it, but they're sent off-site, then we would still register that--

MR. [PANELIST]: The off-site warehouse--yes.

MS. : Okay. If there is only one address, how do I distinguish our section.

MR. [PANELIST]: Your firm name might do that.

MS. : Okay. Thank you.

[Pause.]

MR. : Right now, we have the ability to file prior notice, even if we get documents untimely. And we've been leaving the arrival date blank, so that it wouldn't reject.

At what point will those edits change? Will that be August 12th? Or will it be sooner than that?

MR. [PANELIST]: You know, I--we're shooting for August, but I think, honestly, a lot will depend on how many--you know, what is the registration looking like? How did the outreach go?

None of the people in this room are driving that train. It will be made at the highest possible policy decision about when we turn the switch to do this. I think the date we're looking at right now is August. This information should be submitted now. you should be working toward that. But the fact remains--you know, you have to do this now. When, actually, the agency will say "Enough is enough, we're past education, we can no longer allow any sort of wiggle room in the system if

we're going to do what Congress requires us to do"-we're shooting for August, and we're hoping we're
going to make it. But, you know, you should try to
do it properly now.

MR. [PANELIST]: And we are looking at the data quality of the data stream we're getting now.

MR. : All of the information is put in there. We just don't get it timely from overseas.

MR. [PANELIST]: Yes--no, I do understand what you were saying. But, you know, it now becomes very important that the people overseas have to realize that the mechanism for doing business is going to have to change to comply with this new environment.

Let's--I'm going to repeat something that

Joe said in his presentation. There's now a

two-tiered system in this country for entry review.

There's prior notice. They only give a damn about

one thing: is there credible intelligence that the

product may have been purposefully adulterated to

harm the American citizens? That's very serious

business. And eventually we in Customs will take it very seriously and the people who want to trade with this country are going to have to accommodate that.

MR. : Thank you.

MR. [PANELIST]: And, you know, unfortunately you can tell your foreign suppliers--I mean, "Yes, you can get us the data late now." But there's going to come a point where they're going to get shipments refused.

And now refused is different under the prior notice than the traditional 801(a). Pretty much, unless we made a major mistake, if we do an 801(a) refusal, it's final. "Refused" here can be overcome by supplying the data after it's in secure storage.

The other thing is it's a port-by-port decision by the port director of Customs. Some ports--especially on the border--they don't have the secure facilities. Their answer is going to be: "Make two right turns and head right back to Canada or Mexico." And, you know, that may start

getting people's attention when the truck comes back to their door--or if they're going to have to pay all these extra storage charges with secure facilities.

And the only thing I can say is: the information is known. You have got to get people into the idea of giving it to you a little earlier, or their product will suffer. And that's the only way I can say you can communicate this back to them.

"You want it in here? You've got to give it to us two days, three days--"--whatever it is.

MR. CARSON: And then, once again: this regulation anticipates -- we know how business is done before this regulation. This regulation was written in anticipation that it would require a change in the business environment for importing food into this country.

There is no easier way to say it.
[Pause.]

MS. : If a shipper uses the website to file prior notification, and then the

broker files via ABI, would there be a problem if there is a difference in the product code and HS codes being used--by the broker versus the shipper?

MR. [PANELIST]: Yes.

MS. : Would the entry get rejected? The prior notification need to be done again?

MR. [PANELIST]: Whether it gets rejected or gets elevated to a much higher level of review, I'm--we're not prepared to say at this point. You know, the product codes' being different--we are going to be checking the registration numbers; do they match the other information we're getting on the firms. We're going to be looking at what the product is.

But if somebody tells us it's water, and somebody else tell's us it's salt, we're going to have a major issue of do we trust either of them?

MS. : Well, there's quite a few shippers attempting to do the prior notice themselves. But there's a likelihood of that happening quite a bit--even if it's off by a

number, or whatever.

MR. [PANELIST]: Well--

MS. : Because they're not the experts in determining it. However, they are attempting to file it themselves.

MR. [PANELIST]: Right. And, again, I think it's going to depend on experience; what the degree of difference is. Certain parts of our product code, depending on the industry, are very, very specific. Others are really--you know, is it in paper or in plastic?

And, you know, that gets misinterpreted because it's really the immediate surface contacting the food. And so if you had a plastic-lined wood box, technically, it's plastic. But, you know, a shipper would probably say it's a wood box.

MS. : So it's a wait-and-see type of thing?

MR. CARSON: Yes. I would say so.

MS. : I personally haven't used the website myself, but is the entry number a

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mandatory field?

MR. [PANELIST]: No.

MR. [PANELIST]: In the website you

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wouldn't normally have an entry number--

MS. : PNSI?

MR. : --at that time. So you would give like an airway bill number, or a bill of lading or something like that.

MS. : Okay. And I have heard that it's quite time-consuming and laborious to go through it, especially if you have multiple items. So there are companies out there who are--have, I guess, created templates to make it easier for shippers to file this information. I guess that information will dump into the FDA's system.

Do you know about it? Is there--

MR. [PANELIST]: I'm aware of one Canadian--

MS. : --problems with it, or--

MR. [PANELIST]: --company that is trying that. They're essentially working off of their entry order. Their web-based ordering system is

populating the information they're going to somehow script over to us via prior notice. And I think--you know, I haven't seen the technical details on how they're doing it.

MS. : I'm assuming that's all okay?

MR. [PANELIST]: Yes.

MS. : Okay.

MR. [PANELIST]: I mean, we--

MR. [PANELIST]: They're submitting the data, so they're assuming the accuracy of it so--you know, if I order Product X, and they know what that is, and they pass that on to our web system, I don't see any problem with that.

MR. [PANELIST]: As long as their programming is good.

MS. : But the existing FDA, that the PNSI system, are there any plans to simplify it a bit, or speed it up. Because I believe it retains information for 30 days? Whereas--

MR. [PANELIST]: There's two features.

One is, right now, we're on version 1.1 of the PNSI

system. 1.2 is scheduled for May. So there will be some minor differences when the next version comes out, and a template might fail when the new version comes out.

he other thing is there's a save feature in it where you can fill the stuff in but not submit it. And that's very handy if you're doing multiple submissions and you've got different ways of coming into the country. You can use the "Save" feature and then submit it at the appropriate time so you meet the statutory requirement.

MR. [PANELIST]: Well, you can--can't you recall a previous transaction within 30 days--

MR. [PANELIST]: Well, you don't have to submitted it either, though.

MR. [PANELIST]: Yes.

MR. [PANELIST]: You can just fill it out and save it, and then not submit, and you can do multiple entries that way.

MS. : As far as the 30 days, that will basically stay? I guess the data can stay in there for 30 days?

MR. [PANELIST]: Right.

MS. : Is that right?

MR. [PANELIST]: But people should be aware that there are version differences, you know, coming up in PNSI. And when that happens, the templates might fail.

MR. [PANELIST]: No different than when--you know, when there' a CTARE change, for those people who are filing by ACS.

[Pause.]

MR. : Is the container number a mandatory field on an ocean shipment? Is a bill of lading number sufficient?

MR. [PANELIST]: The container number isn't. I don't think that was one of the required elements.

MR: : Okay. Because there's only room for one container number on--

MR. [PANELIST]: Currently.

MR. : --on their website.

Now, through ABI, we can put multiple containers in. But if we do it on the PNSI--

MR. [PANELIST]: Do you--

MR. : --there's only one

container available.

MR. [PANELIST]: I don't think it's required, but he asked about--there's only room for one container number?

MR. [PANELIST]: [Off mike.] Well, I think that's correct [inaudible].

MR. [PANELIST]: Yes, but I think that's one of the changes that the want to do. I don't know if it's in 1.2.

MR. [PANELIST]: That's one of the changes that they're thinking about with the new version: allowing more container numbers to put there. Because if you--obviously, if you have that information it's better to give it. It's going to be helpful. But I don't believe it's required information, to have a container number.

MR. : Thank you.

MR. [PANELIST]: You're welcome.

[Pause.]

MR. : What does "natural state"

mean? "Food in its natural state?" And I'll give you an example: fish, if it's cut fresh, is it still in its natural state?

MR. [PANELIST]: Yes.

MR: : In other words, prior to cooking or--

MR. [PANELIST]: Yes, prior to any processing considered. If it's in its natural state. It's one of the picks when you build a product code--

MR. [PANELIST]: I think you can gut it, and--

MR. [PANELIST]: If you--

MR. [PANELIST]: --if you take the head off, I think then it's already starting to become processed. I think just--

MR. : Well, I didn't put--we would expect, if you're shipping fish that, you know, it had been eviscerated, and we would consider fish that had been eviscerated still in its natural state.

MR. : I mean, a filet of fish.

MR. [PANELIST]: No. A filet is--you're getting into processing, you start fileting it.

MR. : So it's no longer in a natural--

MR. [PANELIST]: We're taking about fish in the round.

MR: : Uh-huh.

MR. [PANELIST]: If you gut it we would probably consider that "in its natural state," but if you start fileting the product, you are processing it.

MR: : And just like the example you gave, if you've got a packer who's using multiple growers--fish farms--you know, to pack out his product in a box, then he may not be able to identify which grower it is.

MR. [PANELIST]: Correct. But the same thing is if we sample that shipment and find salmonella, then he better not suddenly say, "Oh, that box really came from this farm, and we really know who the other guys are."

He's essentially saying, "Okay. I just

confessed to you that I lied to you."

 $$\operatorname{MR}.$$: Right. Otherwise all farms that supply him become suspect.

MR. [PANELIST]: Right. But, you know, there are true consolidators who get the stuff in, throw them into big bins, you know, and--like, you know, with apples--ship out. So the consolidator is the only person we've got. And if there's pesticide in his stuff, he's out of luck.

MR. : The second question is: I do some work with embassies and "diplomatic pouch"--when I was going like this I was wondering, what does "diplomatic pouch" mean? Are there size constraints, or is that anything ordered by an embassy? So, in other words, if an embassy's throwing a party, and they're ordering--

MR. [PANELIST]: Oh, RF-44--yeah

MR: : --food from overseas.

MR. [PANELIST]: Umm--

MR: : Is that subject to prior

notice?

MR. [PANELIST]: I think it's your second

scenario. If it's going to the embassy, they could pretty much bring in anything they want.

MR. [PANELIST]: Yes.

MR. : Okay. But they don't need to file a prior notice.

MR. [PANELIST]: Nope.

MR. [PANELIST]: We give the embassies very wide latitude. We stay away from them [inaudible].

MS. SETTERBERG: Especially in November when the nouveau Beaujolais comes into the French Embassy, right?

[Pause.]

MR. : Yes. So my question is regarding non-compliance with prior notice and/or registration. What would be an example of some of the civil monetary fines and penalties that we can expect after August?

MR. [PANELIST]: I don't think anybody has gone that far. I mean, there will be compliance policy. But I don't think anybody has--that's unexplored territory at this point.

MS. SETTERBERG: I haven't heard anything about that yet.

MR. : So it hasn't been clearly defined yet?--

MR. [PANELIST]: No.

 $$\operatorname{MR}.$$: --in the interim final rule. Okay. Thank you.

MR. [PANELIST]: We have stated that civil money penalties will be issued based on the type of violation. We probably will never tell you exactly how much that is, because it's going to be on a case-by-case basis. And we're going to determine whether it's been, you know, a flagrant violation and you continue to do that, or it's just a one-time.

So everything will be done proportionate to the violation. I doubt that you'll see a list of penalties, like a list of how much jewelry costs. I mean, we're not going to go into that kind of detail.

MS. SETTERBERG: Okay. Any other questions?

[No response.]

Let me just ask the panelists: anything else you want to add in sum?

Lou?

Okay.

I thank you especially for this group, for waiting 'til the very end. Those of you who do want to work with this for registration today, it's Room 106--right? And that's--what?--straight across the Atrium, down the hallway? And Larry will be there to work with you. Joe will be around for a little bit longer, too, if you have any specific prior notice questions.

I would ask all of you who work with various firms that may have to register, if you check with them and see that they have or haven't. We're really trying to work this. We've got a ways to go yet to get all the firms registered that need to, and anything you can do to help us in that regard would be useful.

Keep your eye on the website for any notifications that might change what's going on or

update what goes on. There's lots of information there. You have a lot of information in your packet.

And now you probably know as much as we do about all of this--except for Joe's few examples about actually what's happening, as he sees it at the port.

So, do ask the questions. Call the numbers if you have any questions, and that will help us make it all better.

So thank you for coming today.

[Applause.]

[Session concluded.]

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